UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/542,935	04/04/2000	Maria Palasis	02844/56301	5876

26646 7590 06/04/2003

KENYON & KENYON
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	10

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/542,935	PALASIS, MARIA	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-31,34-38,40-52,54-56,58 and 59* is/are pending in the application.

4a) Of the above claim(s) *2,4-8,13-16,21,22,28,29,31,40,41,45,46 and 48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,10-12,17-20,23-27,30,34-38,42-44,47,49-52,54-56,58 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Final Rejection

Claims 1-8, 10-31, 34-38, 40-52, 54-56, 58, and 59 are pending.

Applicant's traversal, the amendment to the specification, the amendment to clams 1, 25, 26, 49, 50 and 51, and the cancellation of claims 9, 32, 33, 39, 53, and 57 in paper no. 9 filed on 3/17/03 is acknowledged and considered.

In an apparent oversight, the examiner grouped claims 23 and 25 with the non-elected species. Thus, claims 23 and 25 are rejoined with the elected invention.

In view of a search of the prior art, claim 49 will be rejoined with the elected embodiment.

This application contains claims 2, 4-8, 13-16, 21, 22, 28, 29, 31, 40, 41, 45, 46, and 48 drawn to an invention nonelected without traverse in Paper No. 6 filed on 10/4/02. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

The insertion "This Application is a CIP of US 09/204,254 filed on 12/3/98 now US Patent 6,369,039" on the first line of the specification is acknowledged.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: the claims are not supported under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons set forth below.

Information Disclosure Statement

Each U.S. Patent cited on the IDS in paper no. 8 filed on 3/17/03 was considered and initialed on the 1449 by the examiner. However, if the application was allowed the U.S. patents would not be printed on the patent. If the applicants want the US Patents to be printed should the application be in condition for allowance, the applicants should submit a 1449 listing the class/subclass for each US Patent listed on the 1449 filed on 3/17/03.

The international search report has been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 10-12, 17-20, 22-27, 30, 34-38, 42-44, 47, 49-52, 54-56, 58, and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claims 1 and 26 filed on 3/17/03 introduce new subject matter into the application.

The original specification did not disclose making and using a medical device comprising a biocompatible structure carrying a genetic material, said biocompatible structure comprising a polymeric coating that coats at least a portion of said structure, said genetic material comprising: a) a first therapeutic agent comprising a vector containing a first polynucleotide encoding an angiogenic agent and b) a second therapeutic agent comprising a non-genetic therapeutic agent, wherein said non-genetic therapeutic agent is an angiogenic agent. No page is cited for support of the amended claims. MPEP 714.02 states, "Applicant should also specifically point out the support for any amendments made to the disclosure. See MPEP § 2163.06."

In addition, the specification set forth a list of products that the vector and the carrier can carry (pages 16-19). However, nothing in the specification would lead one to the particular combination set forth in the amended claims. "It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose." *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961, 1966 (CAFC 1997).

Applicant's arguments with respect to claims 1, 3, 10-12, 17-20, 22-27, 30, 34-38, 42-44, 47, 49-52, 54-56, 58, and 59 have been considered but are moot in view of the new ground(s) of rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 30 remains and claims 17, 37, 50, 52, and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 recites the limitation "said biocompatible carrier" in line 13, page 32. There is insufficient antecedent basis for this limitation in the claim.

Applicant's arguments with respect to claim 17 have been considered but are moot in view of the new ground(s) of rejection.

Claim 30 recites the limitation "said non-plasmid vector" in line 6, page 34. There is insufficient antecedent basis for this limitation in the claim. Claim 30 depends on claim 26 and claim 26 does not recite a non-plasmid vector.

Applicant's arguments filed 3/17/03 have been fully considered but they are not persuasive. Applicant claims to have canceled claim 30 without prejudice (see page 4). However, applicant did not cancel claim 30 (See page 1 of the amendment filed on 3/17/03).

Claim 37 recites the limitation "said carrier" in line 12, page 35. There is insufficient antecedent basis for this limitation in the claim.

Applicant's arguments with respect to claim 37 have been considered but are moot in view of the new ground(s) of rejection.

The term “small molecule" in claim 50 is a relative term, which renders the claim indefinite. The term “small molecule" is not defined by the claim, the specification does not

provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The disclosure does not define the metes and bounds of the term. One skilled in the art understands that there are molecules that are considered a small molecule (e.g. DNA, RNA, organic compound, peptide, inorganic compounds, etc.) and the disclosure does not claim or particularly point out what is a small molecule.

Applicant's arguments with respect to claim 50 have been considered but are moot in view of the new ground(s) of rejection.

The term "vector is site specific" in claims 52 and 56 is a relative term, which render the claims indefinite. The term "site specific" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The disclosure does not define the metes and bounds of the term. One skilled in the art understands that vectors can be modified to selectively replicate or selectively target a site in a mammal and the disclosure does not claim or particularly point out which definition of the term is being used.

Applicant's arguments with respect to claims 52 and 56 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

Applicant's arguments, see paper no. 9, filed on 3/17/03, with respect to the 102(b) have been fully considered and are persuasive. The rejection of claims 1, 9, 10, 11, 12, 17, 19, 20, 24,

26, 32, 33, 34, 35, 36, 37, 39, 42, 44, 47, 50, 51, 52, 53, 54, 55, 56, 57, 58, and 59 under 35 U.S.C. 102(b) as being anticipated by Donovan et al. (US Patent No. 5,833,651) has been withdrawn because of the amendment to the independent claims and the cancellation of claims 9, 32, 33, 39, 53 and 57. However, upon further consideration, a new ground(s) of rejection is made in view of Isner (US 5,652,225).

Applicant's arguments, see paper no. 9, filed on 3/17/03, with respect to the 102(e) have been fully considered and are persuasive. The rejection of claims 1, 9, 10, 11, 12, 17, 19, 20, 24, 26, 32, 33, 34, 35, 36, 37, 39, 42, 44, 47, 50, 51, 52, 53, 54, 55, 56, 57, 58, and 59 under 35 U.S.C. 102(b) as being anticipated by Palasis et al. has been withdrawn because of the amendment to the priority of the instant application.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 11, 12, 19, 24, 26, 30, 34, 35, 37, 44, 49, 50, 52, 54, 55, 56, 58, and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Isner (US 5,652,225). Isner teaches a method for delivery of an angiogenic factor combined with other angiogenic genes or gene products to an arterial cell comprising contacting the cell with a hydrophilic polymer (hydrogel polymer) incorporating the nucleic acid (columns 1, line 66- column 2, line 7 and column 7, lines 1-14). The hydrophilic polymer is delivered to an arterial cell using any means familiar to the skill artisan, e.g., catheter or rods (column 7, lines 42-55). The nucleic acid can be carried by a

microdelivery vehicle such as cationic liposomes or a viral vector (column 2, lines 34-36). Isner further teaches a method of treating restenosis using the polymer (column 5, lines 1-15).

Applicant's arguments with respect to Claims 1, 10, 11, 12, 19, 24, 26, 30, 34, 35, 37, 44, 49, 50, 52, 54, 55, 56, 58, and 59 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

Applicant's arguments, see paper no. 9, filed on 3/17/03, with respect to the 103(a) have been fully considered and are persuasive. The rejection of Claims 1, 3, 26, and 27 under 35 U.S.C. 103(a) as being unpatentable over Donovan et al. (US Patent No. 5,833,651) taken with Branellec et al. (US Patent No. 5,851,521) has been withdrawn because of the amendment to the independent claims.

Applicant's arguments, see paper no. 9, filed on 3/17/03, with respect to the 103(a) have been fully considered and are persuasive. The rejection of Claims 1, 18, 26, and 43 under 35 U.S.C. 103(a) as being unpatentable over Donovan et al. (US Patent No. 5,833,651) taken with Lennox (US Patent No. 6,280,411) has been withdrawn because of the amendment to the independent claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or non-obviousness.

Claims 1, 17, 19, 20, 26, 42, 44, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isner (US Patent No. 5,652,225) in further view of Donovan et al. (US Patent No. 5,833,651). Isner teaches a method for delivery of an angiogenic factor combined with other angiogenic genes or gene products to an arterial cell comprising contacting the cell with a hydrophilic polymer (hydrogel polymer) incorporating the nucleic acid (columns 1, line 66-column 2, line 7 and column 7, lines 1-14). The hydrophilic polymer is delivered to an arterial cell using any means familiar to the skill artisan, e.g., catheter or rods (column 7, lines 42-55). The nucleic acid can be carried by a microdelivery vehicle such as cationic liposomes or a viral vector (column 2, lines 34-36). Isner further teaches a method of treating restenosis using the polymer (column 5, lines 1-15). However, Isner does not specifically teach making and using a medical device comprising a biocompatible structure carrying a genetic material, wherein the structure is a metallic stent.

However, at the time the invention was made, Donovan teaches a device comprising a stent to deliver virus to the wall of a lumen for gene delivery (column 2, line 65-column 4, line 35). More specifically, the stent has a polymer composition comprising fibrin, the composition

covering at least a portion of the lumen wall-contacting surface of the stent. The virus can be an adenovirus or a retrovirus and the virus is capable of expressing a protein in a cell and a liposome can be incorporated in to the polymer-coated stent (column 10, line 35-column 11, line 67). The device can further comprise a biodegradable second polymer composition covering at least a portion of the first polymer composition on the lumen wall-contacting surface. The polymeric carriers can be used to control and sustain delivery (column 3-column 6). Donovan further teaches using different types of stents, including metal stents (column 5, line 55-column 8, line 65). In addition, Donovan teaches a method of delivering nucleic acid to cells using the device described above (columns 20-22, claims 21-28). Furthermore, Donovan cites methods for using a spray application to cover the stent (column 10, lines 9-10).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Isner in further view of Donovan to make and use a medical device comprising a biocompatible structure carrying a genetic material, said biocompatible structure comprising a polymeric coating that coats at least a portion of said structure, said genetic material comprising: a) a first therapeutic agent comprising a viral vector containing a first polynucleotide encoding an angiogenic agent and b) a second therapeutic agent comprising a non-genetic therapeutic agent, wherein said non-genetic therapeutic agent is an angiogenic agent, wherein said structure is a metallic stent. One of ordinary skill in the art would have been motivated to make the medical device to improve delivery of angiogenic agents. Furthermore, one of ordinary skill in the art would have been motivated to use a metallic stent in the method of controlled delivery of genetic material to improve delivery of angiogenic

agents to a mammal because metallic stents were known in the art for delivering a vector comprising a nucleic acid to a mammal.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments with respect to Claims 1, 17, 19, 20, 26, 42, 44, and 47 have been considered but are moot in view of the new ground(s) of rejection.

Claims 1, 3, 24, 25, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isner (US Patent) taken with Branellec et al. (US Patent No. 5,851,521). Isner teaches a method for delivery of an angiogenic factor combined with other angiogenic genes or gene products to an arterial cell comprising contacting the cell with a hydrophilic polymer (hydrogel polymer) incorporating the nucleic acid (columns 1, line 66- column 2, line 7 and column 7, lines 1-14). The hydrophilic polymer is delivered to an arterial cell using any means familiar to the skill artisan, e.g., catheter or rods (column 7, lines 42-55). The nucleic acid can be carried by a microdelivery vehicle such as cationic liposomes or a viral vector (column 2, lines 34-36). Isner further teaches a method of treating restenosis using the polymer (column 5, lines 1-15). However, Isner does not specifically teach using an adeno-associated viral (AAV) vector in the device or a method of treating restenosis comprising delivering a nucleic acid and a non-genetic agent to a cell using said device. In addition, Isner does not specifically teach a method of treating restenosis in a site of mechanical injury to an arterial wall produced by treatment of an atherosclerotic lesion by angioplasty.

However, at the time the invention was made, AAV viral vectors were known for delivering nucleic acid to cells using a catheter and using micro-particles (e.g. polylactide) to deliver said nucleic acid (column 9, line 60-column, line 67). Branellec teaches using AAV vectors comprising the protein GAX in a method inhibiting restenosis in a mammal (abstract and column 7, lines 55-65). AAV vectors are able to infect a wide spectrum of cells without inducing any effect on cellular growth, morphology, or differentiation and they do not appear to be involved in human pathologies. Branellec teaches a method of inhibiting vascular smooth muscle cell proliferation and migration at a predetermined site. More preferably, the site is a site of mechanical injury to an arterial wall produced by treatment of an atherosclerotic lesion by angioplasty (column 3).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Isner taken with Branellec, namely to use an recombinant AAV as the viral vector in the device. One of ordinary skill in the art would have been motivated to use an AAV vector in the device because AAV vectors were well known in the art for use in gene delivery of a GAX protein to inhibit restenosis in a patient. In addition, one of ordinary skill in the art would have been motivated to use the device in a method of delivering a nucleic acid (AAV vector comprising a nucleic acid encoding and angiogenic protein) and a non-genetic agent to a cell to avoid one of the problems (targeting desired cells) associated with gene delivery to cells.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Isner taken with Branellec, namely the use the device in a method of treating restenosis in a site of mechanical injury to an

arterial wall produced by treatment of an atherosclerotic lesion by angioplasty. One of ordinary skill in the art would have been motivated to use the device because Branellec teaches that angiogenic agents can be used to treat restenosis in a site of mechanical injury to an arterial wall produced by treatment of an atherosclerotic lesion by angioplasty.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments with respect to claims 1, 3, 24, 25, 26 and 27 have been considered but are moot in view of the new ground(s) of rejection.

Claims 1, 18, 26, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isner (US Patent 5,652,225) taken with Lennox (US Patent No. 6,280,411). Isner teaches a method for delivery of an angiogenic factor combined with other angiogenic genes or gene products to an arterial cell comprising contacting the cell with a hydrophilic polymer (hydrogel polymer) incorporating the nucleic acid (columns 1, line 66- column 2, line 7 and column 7, lines 1-14). The hydrophilic polymer is delivered to an arterial cell using any means familiar to the skill artisan, e.g., catheter or rods (column 7, lines 42-55). The nucleic acid can be carried by a microdelivery vehicle such as cationic liposomes or a viral vector (column 2, lines 34-36). Isner further teaches a method of treating restenosis using the polymer (column 5, lines 1-15). However, Isner does not specifically teach a medical device, wherein the polymer coating is about 1 to about 40 layers having a thickness of about 1 to about 10 μm/layer of coating or using the medical device to deliver a nucleic acid and a non-genetic agent to a cell.

However, at the time the invention was made, Lennox teaches medical devices and methods for the controlled localized delivery of drug agents, such as nucleic acid vectors, to target locations within a mammalian body (column 2, line 35-column 3, line 24). Lennox teaches that the device is typically coated with a polymer that is about 1 to 10 microns in thickness and multiple layers of the polymer coating.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made as routine to combine the teaching of Isner taken with Lennox, namely to coat the device with a polymer that is about 1 to 10 microns in thickness and multiple layers of the polymer coating. One of ordinary skill in the art would have been motivated to use the conditions taught by Lennox for the coating the stent in the device because it is the typical or preferred thickness for coating the device. In addition, the claimed conditions, as evidence to the contrary, do not display an unexpected advantage as compared to using a different thickness of coating.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments with respect to claims 1, 18, 26, and 43 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER